Remarks

Amendments to the Claims

Claim 1 and 6 have been amended to define the drug as incorporated into a water-insoluble carrier containing specific materials. Support for this amendment is found at page 5, lines 1-9, page 6, lines 11-28, page 7, lines11-14, page 14, line 18 to page 15, line 2, page 16, lines 19-28, page 17, lines 1-10. Water insoluble is defined in "The Pharmacopoeia of the United States Twenty-seventh Revision": as "An insoluble compound is one which requires greater than or equal to 10,000 parts of solvent (in this case, water) for 1 part of solute".

Claim 2 has been amended as an independent claim defining the carrier as slowly water soluble (page 14, lines 16-18) or water insoluble when the drug is a lipophilic derivative.

Claims 4-7 now depend directly or indirectly from claim 2.

Claims 14 and 30-32 have been cancelled.

New claims 33-38 have been added.

Support for claim 33 is found at page 8, line 26 to page 10, line 18.

Support for claims 34 and 35 is found at page 14, lines 5-12.

Support for claims 36 and 37 is found at page 12, lines 25-29

Support for claim 38 is found at page 14, lines 26-29

Rejection under 35 U.S.C. 103

Claims 1-13, 15-28 were rejected as obvious under 35 U.S.C. 103 over U.S. Patent No. 5,952,005 in view of U.S. Patent No. 5,756,483. This rejection is respectfully traversed.

U.S. Patent No. 5,952,005

'005 teaches the coating of drug/excipients with water-insoluble ethyl cellulose and a water-soluble material such as HPMC in order to achieve a sustained release dosage form. In contrast, our application teaches the use of at least one enzymatically degradable coating materials to produce an "abuse-deterrent" dosage form. Section D of our specification, paragraphs 0053-0057, describes coating materials and methods of coating which can be used to create water-insoluble and enzymatically degradable coatings. These coating materials and methods are not described in '005.

U.S. Patent No. 5,756,483

'483 teaches the nasal administration of a drug in combination with cyclodextrin (preferably methylated beta-cyclodextrin) or polysaccharide in order to improve the stability or bioavailability of the drug. The claims and specification disclose the formation of a complex between a drug and a poorly water soluble cyclodextrin (eg, ethylated beta-cyclodextrin) in order to achieve a lipophilic derivative of the drug (See paragraph 0040). Based on the teachings of '483, it would not have been obvious to one of ordinary skill in the art to complex of a drug with a cyclodextrin in order to form a lipophilic derivative of the drug.

Neither reference discloses incorporation of the claimed lipophilic materials to make either a lipophilic derivative of a drug, or a formulation that is lipophilic or water insoluble through the inclusion of these lipophilic materials, to make it more abuse resistant.

Favorable consideration of claims 1-13, 15-29 and 33-38 is respectfully solicited.

Respectfully submitted,

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